IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

MALLINCKRODT INC. and LIEBEL-FLARSHEIM COMPANY Plaintiffs, vs. E-Z-EM, INC. and ACIST MEDICAL SYSTEMS, INC. Defendants	Civil Action No. 2:07-CV-262 (TJW)

FOURTH AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF E-Z-EM, INC. AND ACIST MEDICAL SYSTEMS, INC. TO MALLINCKRODT INC. AND LIEBEL-FLARSHEIM COMPANY'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND TO THE COURT'S ORDER JOINING ACIST MEDICAL SYSTEMS, INC. AS A DEFENDANT PURSUANT TO FED. R. CIV. P 25(C)

Defendants E-Z-EM, Inc. and ACIST Medical Systems, Inc. (collectively "E-Z-EM") respond as follows to the numbered paragraphs of the First Amended Complaint for Patent Infringement ("First Amended Complaint") filed by Mallinckrodt Inc. and Liebel-Flarsheim Company ("Plaintiffs") and to the Court's Order Joining ACIST Medical Systems, Inc. as a Defendant Pursuant to Fed. R. Civ. P 25(c).

THE PARTIES

1. E-Z-EM lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 1 of the First Amended Complaint, and therefore denies the same.

2. E-Z-EM lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 2 of the First Amended Complaint, and therefore denies the same.

3. E-Z-EM admits the allegations set forth in Paragraph 3 of the First Amended Complaint.

JURISDICTION

4. E-Z-EM admits this action arises under the Patent Act of the United States, 35 U.S.C. §§ 1 *et seq.*, and that this court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that it has violated any provision of 35 U.S.C. §§ 1 *et seq.*

5. E-Z-EM admits the allegations set forth in Paragraph 5 of the First Amended Complaint.

6. E-Z-EM denies the allegations set forth in Paragraph 6 of the First Amended Complaint.

VENUE

7. E-Z-EM admits that venue is proper pursuant to 28 U.S.C. §§ 1391 and/or 1400, and denies all other allegations set forth in Paragraph 7 of the First Amended Complaint.

8. E-Z-EM denies the allegations set forth in Paragraph 8 of the First Amended Complaint.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,868,710

9. E-Z-EM admits that the face of U.S. Patent No. 5,868,710 ("'710 patent") shows an issue date of February 9, 1999, that the patent is entitled "Medical Fluid Injector," and that it lists the named individuals as purported inventors. E-Z-EM denies that the '710 patent was duly and legally issued. E-Z-EM denies the allegation that Mallinckrodt, Inc. is the implied exclusive licensee of the '710 patent. Upon information and belief, Plaintiff Mallinckrodt, Inc. lacks standing and thus is not a proper party to this action. E-Z-EM lacks sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 9, and therefore denies the same.

10. The allegations contained in Paragraph 10 are conclusions of law to which no response is required; however, to the extent that any response is required, the allegations are denied.

11. E-Z-EM denies the allegations set forth in Paragraph 11 of the First Amended Complaint.

12. E-Z-EM denies the allegations set forth in Paragraph 12 of the First Amended Complaint.

13. E-Z-EM denies the allegations set forth in Paragraph 13 of the First Amended Complaint.

14. E-Z-EM denies the allegations set forth in Paragraph 14 of the First Amended Complaint.

15. E-Z-EM denies the allegations set forth in Paragraph 15 of the First Amended Complaint.

16. E-Z-EM denies the allegations set forth in Paragraph 16 of the First Amended Complaint.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth herein, and without admitting any allegations of the First Amended Complaint not otherwise admitted, E-Z-EM avers and asserts the following Affirmative Defenses to the First Amended Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement)

17. The manufacture, use, and/or sale of the EmpowerCT, EmpowerCTA and EmpowerMR injectors does not infringe, has not infringed, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '710 patent, nor has E-Z-EM induced or contributorily infringed a valid and enforceable claim of the '710 patent.

SECOND AFFIRMATIVE DEFENSE
(Laches)

18. Plaintiffs' claims are barred under the doctrine of laches as Plaintiffs have not diligently pursued the patent infringement claims stated in its First Amended Complaint.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

19. The '710 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 101 *et seq.*

FOURTH AFFIRMATIVE DEFENSE
(Equitable Estoppel)

20. Plaintiffs' claims are barred under the doctrine of equitable estoppel.

FIFTH AFFIRMATIVE DEFENSE
(Statute of Limitations)

21. Under 35 U.S.C. § 286, Plaintiffs are barred from recovering for any act of infringement that occurred more than six years prior to the filing of the First Amended Complaint.

SIXTH AFFIRMATIVE DEFENSE
(Failure to Mark Patent)

22. Plaintiffs have failed to mark their products regarding their use of the '710 patent and therefore are barred from recovering damages under 35 U.S.C. § 287(a).

23. Plaintiffs first gave E-Z-EM actual notice of the '710 patent on June 20, 2007.

SEVENTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

24. Plaintiffs' First Amended Complaint fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE
(Inequitable Conduct)

25. The '710 patent is void, unenforceable and of no legal effect due to an ongoing and repeated pattern of inequitable conduct committed during the prosecution of the application that matured into the '710 patent.

26. The '710 patent matured from U.S. Patent Application Serial No. 08/753,288 ("the '288 application").

27. Title 37 of the Code of Federal Regulations § 1.56 and the Manual of Patent Examining Procedure § 2000.01 *et seq*. impose a duty of candor and good faith on each individual associated with the filing and prosecution of a patent application before the U.S.P.T.O.

28. Liebel-Flarsheim, the named inventors, persons substantially involved in the prosecution of the ’288 application and/or those acting on their behalf had a duty to disclose to the U.S.P.T.O. all information known to them to be material to the patentability of the application under examination under 37 C.F.R § 1.56.

29. Each of the named inventors on the ’288 application, namely Dane Battiato, Gary Wagner, Steve Verdino, Robert Bergen, James Knipfer, Pamela Jacobs, Peter Staats, John Minnich, Charles Neer, James Goethel, and Mitchell Stern, signed an inventor declaration acknowledging their duty of candor under 37 C.F.R. § 1.56 between December 12, 1996 and December 16, 1996, and acknowledged that all information material to patentability of the invention had been disclosed to the United States Patent and Trademark Office (“U.S.P.T.O.”).

30. Each of the named inventors on the ’288 application, namely Dane Battiato, Gary Wagner, Steve Verdino, Robert Bergen, James Knipfer, Pamela Jacobs, Peter Staats, John Minnich, Charles Neer, James Goethel, and Mitchell Stern, understood or should have understood their duty of candor under 37 C.F.R. § 1.56 when they signed their inventor declarations in December, 1996.

31. Each of the named inventors on the ’288 application were familiar with their obligation to disclose all information known to them to be material to patentability having each signed a similar declaration that had been filed with the U.S.P.T.O., namely:

a. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Dane Battiato had signed an inventor's declaration in United States Patent Application Serial Number ("U.S.S.N.") 08/753,283 on November 19, 1996.

b. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Gary Wagner had signed an inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996.

c. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 16, 1996, Steve Verdino had signed an inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996.

d. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Robert Bergen had signed an inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996 and another inventor's declaration in U.S.S.N. 07/144,448 in 1988.

e. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, James Knipfer had signed an inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996.

f. Prior to signing the inventor's declaration for the '288 application acknowledging her duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Pamela Jacobs had signed an inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996; another inventor's declaration in U.S.S.N. 07/741,884 in 1991; and a further inventor's declaration in U.S.S.N. 08/021,935 in 1993.

g. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Peter Staats had signed an inventor's declaration in U.S.S.N. 06/439,860 in 1982.

h. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, John Minnich had signed an inventor's declaration in U.S.S.N. 07/733,521 in 1991.

i. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Charles Neer had signed an inventor's declaration in U.S.S.N. 07/712,110 in 1991; another inventor's declaration in U.S.S.N. 07/881,782 in 1992; a further inventor's declaration in U.S.S.N. 08/195,382 in 1994; and a still further inventor's declaration in U.S.S.N. 08/392,036 in 1995.

j. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office

on December 12, 1996, James Goethel had signed an inventor's declaration in U.S.S.N. 05/766,256 in 1977; another inventor's declaration in U.S.S.N. 06/825,473 in 1986; a further inventor's declaration in U.S.S.N. 07/712,110 in 1991; and a still further inventor's declaration in U.S.S.N. 08/753,283 on November 19, 1996.

k. Prior to signing the inventor's declaration for the '288 application acknowledging his duty to disclose to the U.S. Patent and Trademark Office on December 12, 1996, Mitchell Stern had signed inventor's declarations in U.S.S.N. 08/178,891 and U.S.S.N. 08/196,709 in 1994.

32. On November 22, 1996, Mr. Thomas Humphrey, from the law firm of Wood, Herron & Evans LLP filed the '288 application. Mr. Humphrey filed the signed declarations of named inventors Dane Battiato, Gary Wagner, Steve Verdino, Robert Bergen, James Knipfer, Pamela Jacobs, Peter Staats, John Minnich, Charles Neer, James Goethel, and Mitchell Stern in the U.S.P.T.O. on January 20, 1997.

33. Dane Battiato, Gary Wagner, Steve Verdino, Robert Bergen, James Knipfer, Pamela Jacobs, Peter Staats, John Minnich, Charles Neer, James Goethel, and Mitchell Stern were each individually subject to the duty of candor imposed upon each individual associated with the filing and prosecution of the '288 application before the U.S.P.T.O.

34. Liebel-Flarsheim's patent attorney who prosecuted the '288 application before the U.S.P.T.O., Mr. Thomas Humphrey, U.S.P.T.O. Registration No. 34353, was subject to the duty of candor imposed upon each individual associated with the filing and prosecution of the '288 application before the U.S.P.T.O.

35. On at least December 12, 1996, Mr. Humphrey had a duty to inform Dane Battiato, Gary Wagner, Steve Verdino, Robert Bergen, James Knipfer, Pamela Jacobs, Peter Staats, John Minnich, Charles Neer, James Goethel, and Mitchell Stern of (i) their obligations to disclose material information to the U.S.P.T.O. under 37 C.F.R. § 1.56 and (ii) what information they needed to provide to him to fulfill their duty of candor under 37 C.F.R. § 1.56.

36. On at least December 12, 1996, with an intent to avoid learning of information that might be material to the examination of the ’288 application and thereby intentionally withhold material information from the Examiner, Mr. Humphrey did not satisfy his obligation to convey to at least Steve Verdino, Charles Neer, Gary Wagner and Pamela Jacobs the significance of the representations they were making upon signing their inventor’s oaths.

37. Mr. Humphrey received the August 17, 1998 Notice of Allowability in the ’288 application on, or about, August 20, 1998.

38. Mr. Humphrey did not send a copy of the August 17, 1998 Notice of Allowability to each of the named inventors.

39. Mr. Humphrey did not send a copy of the August 17, 1998 Notice of Allowability to each of the named inventors to avoid learning that any of the inventors knew of information that was inconsistent with the Examiner’s reasons for allowance and that “a reasonable Examiner would be substantially likely to consider important in deciding whether to allow the application to issue as a patent . . . .”

40. Several named inventors, specifically, James Goethel, Gary Wagner, Dane Battiato, Charles Neer, James Knipfer, Steve Verdino, Peter Staats, Robert Bergen, Pamela Jacobs and Mitchell Stern, and their attorneys and appointed representatives acting on their

behalf before the U.S.P.T.O., including Thomas Humphrey, violated their duty of candor with an intent to deceive or mislead the U.S.P.T.O. by knowingly, willfully, and deliberately failing to disclose to the U.S.P.T.O. and/or hiding from the U.S.P.T.O. material information and/or making material misrepresentations or omissions during the prosecution of the '288 application with respect to the following prior art: (i) Liebel-Flarsheim's Angiomat 6000 injector system ("the Angiomat 6000"), (ii) Liebel-Flarsheim's Angiomat CT injector system ("the Angiomat CT"), (iii) Liebel-Flarsheim's CT 9000 injector system ("the CT 9000"); and (iv) E-Z-EM Inc.'s PercuPump II injector system ("the PercuPump II").

41. The Angiomat 6000, the Angiomat CT, and the CT 9000 were each prior art power injectors manufactured by Plaintiff Liebel-Flarsheim and publicly used in the United States, known in the United States, offered for sale, and/or sold in the United States and/or described in printed publications more than one year prior to the filing date of the '710 patent (*i.e.*, prior to November 22, 1995).

42. Defendant E-Z-EM's PercuPump II injector system included a prior art power injector that was publicly used in the United States, known in the United States offered for sale, and/or sold in the United States and/or described in printed publications more than one year prior to the filing date of the '710 patent (*i.e.*, prior to November 22, 1995).

43. At least two of the named inventors, Messrs. Staats and Battiato, and Liebel-Flarsheim's attorney, Mr. Thomas Humphrey, further violated their duty of candor with an intent to deceive or mislead the U.S.P.T.O. by knowingly, willfully, and deliberately failing to disclose to the U.S.P.T.O. during the prosecution of the '288 application a highly material written opinion from the European Patent Office regarding the related PCT International Application No. PCT/US97/21027 ("the '027 PCT application") with an intent to mislead the

Examiner, as well as failing to disclose to the U.S.P.T.O. the amendment filed with respect to the ’027 PCT application.

44. The ’027 PCT application was filed on November 18, 1997 and claimed priority to the ’288 application.

45. The ’710 patent is currently in reexamination, namely Reexamination Control No. 90/009445 (the “’455 Reexam”).

46. The ’455 Reexam was declared on declared on May 29, 2009.

47. The Rules of Practice in Patent Cases (37 C.F.R. § 1.1 *et seq.*) provide that a Patent Owner should provide any material prior art to the Examiner within two months of the date that Reexamination is declared. 37 C.F.R. § 1.555 (“*Any information disclosure statement . . . should be filed within two months of the date of the order for reexamination ....*”).

48. Mr. Humphrey is prosecuting the ’455 Reexam on behalf of the patent owner (Plaintiff Liebel-Flarsheim).

49. Neither Mr. Humphrey, nor any other person on behalf of Plaintiff Liebel-Flarsheim provided an information disclosure statement within two months of the date of the order for reexamination.

50. On September 26, 2009, the PTO issued an Office Action rejecting Claims 9, 10 and 11 as not patentable.

51. Mr. Humphrey conducted several interviews with one or more of the Examiners charged with the ’455 Reexamination between November 18 and 25, 2009.

52. On November 25, 2009, Mr. Humphrey filed multiple “Information Disclosure Statements” and sent thousands of pages of patents and printed publications to the PTO under the cover of these Information Disclosure Statements. Mr. Humphrey did not provide the PTO

with any guide to the import of any of the information contained in the thousands of pages he dumped on the PTO.

53. Subsequently, Mr. Humphrey filed several additional Information Disclosure Statements. Mr. Humphrey has yet to provide the PTO with any guide to the import of any of the information contained in the thousands of pages he dumped on the PTO.

54. Mr. Humphrey has also provided the PTO with thousands of pages of deposition transcripts from this litigation. Again, Mr. Humphrey has not provided the PTO with any guide to the import of any of the information contained in the thousands of pages of deposition transcripts he dumped on the PTO.

55. Mr. Humphrey's actions in deluging the PTO with information without any direction as to the import of any of the information in the flood is further evidence of Mr. Humphrey's intent to deceive the PTO.

The '710 Patent

56. The '710 patent discloses a power head of a power injector using a tilt sensor in electrical communication with a control circuit. The motor and display of the disclosed power head are responsive to a tilt sensor that detects the tilt angle of the power head.

57. The '710 patent has twelve claims, of which two, Claims 1 and 9, are in independent form.

58. Claim 1 of the '710 patent includes the following elements: a plunger drive ram, a motor for moving said plunger drive ram, a syringe mounting for attachment to a syringe to position a syringe relative to said injector to permit said plunger drive ram to engage and move a plunger into or out of a syringe, an electronic display displaying information regarding the activities and state of operation of said injector, said display capable of displaying information

in at least a first and a second orientation, a tilt sensor generating a tilt angle signal indicative of an angle of tilt of the injector relative to the Earth, a control circuit connected to said motor and said display controlling said motor to move said ram and plunger to inject fluid from said syringe, and generating display information and delivering said display information to said display, wherein the display is responsive to said tilt angle signal to display information in a first orientation in response to a first range of values of said tilt angle signal and to display information in a second orientation in response to a second range of values of said tilt angle signal.

59. Claim 9 of the ’710 patent includes the following elements: a plunger drive ram, a motor for moving said plunger drive ram, a syringe mounting for attachment to a syringe to position a syringe relative to said injector to permit said plunger drive ram to engage and move a plunger into or out of said syringe, a tilt sensor generating a tilt angle signal indicative of the angle of tilt of the injector relative to the Earth, and a control circuit responsive to said tilt angle signal to determine a speed of motion of said motor.

Plaintiffs and Their Attorney Withheld Material Information Regarding Liebel-Flarsheim’s Angiomat 6000 Injector With an Intent to Mislead the Examiner

60. Plaintiff Liebel-Flarsheim and, specifically, five of the named inventors on the ’710 patent, James Goethel, Steve Verdino, James Knipfer, Gary Wagner and Charles Neer, and their attorney, Mr. Thomas Humphrey, knowingly, willfully and deliberately withheld or hid relevant and material information regarding Liebel-Flarsheim’s prior art Angiomat 6000 injector with an intent to mislead the Examiner during the prosecution of the ’710 patent.

61. Prior to the filing date of the ’710 patent, Mr. Goethel was “Project Manager, Angiography” at Liebel-Flarsheim.

62. In his role as Project Manager, Angiography, Mr. Goethel had knowledge of Liebel-Flarsheim's Angiomat 6000 injector and its features prior to November 22, 1995 ("the Critical Date"). Mr. Goethel had worked on the development of the Angiomat 6000 prior to the Critical Date. (Goethel Dep. Tr. 38:6-8, 39:17-19).

63. Mr. Goethel confirmed in a declaration he submitted to the United States Patent and Trademark Office on April 9, 1996 during the prosecution of U.S. Patent Application Serial No. 08/467,696 that he was "familiar with the 'Angiomat 6000' injector sold by L-F prior to 1990 through my experience as an employee of L-F."

64. Mr. Knipfer worked on the electronics for the Angiomat 6000, including switches, controls and circuit boards prior to the filing date of the '710 patent. (Knipfer Dep. Tr. 15:14-17:8)

65. Mr. Wagner was responsible for the manufacturing of the Angiomat 6000 and had knowledge of the Angiomat 6000 and its operation prior to the filing date of the '710 patent. (Wagner Dep. Tr. 16:24-17:14; 18:23-19:6; 19:23-21:4).

66. Prior to the Critical Date, Messrs. Goethel, Verdino, Knipfer, Wagner and Neer had knowledge of relevant features and functionalities of the Angiomat 6000 that were material to the prosecution of at least independent claim 9 and dependent claims 6, 10 and 11 of the '710 patent. Specifically,

a. prior to the Critical Date, Messrs. Goethel, Verdino, Knipfer, Wagner and Neer knew that the Angiomat 6000 included at least one mercury switch to detect the position of the powerhead. (Goethel Dep. Tr. 39:17-19, 134:23-135:22) (Neer Dep. Tr. 33:14-19; 40:9-41:22) (Knipfer Dep. Tr. 45:20-46:9;

83:7-11; 98:19-99:18) (Wagner Dep. Tr. 112:9-10; 112:20-113:9; 115:5-116:14).

b. Messrs. Goethel, Verdino, Knipfer, Wagner and Neer knew prior to the Critical Date that the mercury switch would detect if the injector head was pointed upward in essentially in a vertical position. (Goethel Dep. Tr. 112:14-25) (Neer Dep. Tr. 40:9-23) (Knipfer Dep. Tr. 83:7-11; 99:13-18) (Wagner Dep. Tr. 112:20-116:9).

c. Messrs. Goethel, Verdino, Knipfer, Wagner and Neer knew prior to the Critical Date that the Angiomat 6000 included a "required fill sequence" which required the operator to run the plunger to zero, move the powerhead to the vertical position and retract the plunger back into the powerhead to fill the syringe. (Goethel Dep. Tr. 65:18-66:21, 111:10-13) (Neer Dep. Tr. 40:9-23) (Knipfer 81:20-83:11).

d. Messrs. Goethel, Verdino, Knipfer, Wagner and Neer knew prior to the Critical Date that the "required fill sequence" in the Angiomat 6000 used at least one mercury switch to detect the position of the powerhead. (Goethel Dep. Tr. 112:19-114:4) (Neer Dep. Tr. 40:9-23) (Knipfer Dep. Tr. 81:20-83:18).

e. Messrs. Goethel, Verdino, Knipfer, Wagner and Neer knew prior to the Critical Date that the Angiomat 6000 could not be enabled to perform an injection unless the required fill sequence was first performed. (Goethel Dep. Tr. 112:19-114:4) (Neer Dep. Tr. 66:12-69:9) (Knipfer Dep. Tr. 81:20-82:5).

67. Despite Messrs. Goethel, Verdino, Knipfer, Wagner and Neer being knowledgeable of the Angiomat 6000 and its relevant features prior to the Critical Date, they did not provide to the U.S.P.T.O. known, detailed specifications and functionalities of the Angiomat 6000 which corresponded to the claimed subject matter of the '288 application. These specifications and functionalities had been published by Liebel-Flarsheim in the Angiomat 6000 Operator's Manual, the Angiomat 6000 Installation and Service Manual and the Angiomat 6000 Parts Manual well prior to the Critical Date.

68. During the prosecution of the '288 application, with regard to the Angiomat 6000 injector, Liebel-Flarsheim through their attorney, Mr. Humphrey, selectively disclosed to the Examiner as prior art only (1) a marketing brochure for the Angiomat 6000 that included a limited technical disclosure and (2) U.S. Patent No. 4,695,271 ("the Goethel '271 patent") all with an intent to mislead the Examiner. *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *20 (E.D. Tex. 2009) (holding that selective disclosure is strong evidence of intent to mislead the U.S.P.T.O.).

69. The Angiomat 6000 marketing brochure omitted known, detailed specifications and functionalities of the Angiomat 6000 which corresponded to the claimed subject matter of the '288 application. In particular, the marketing brochure that was submitted to the U.S.P.T.O. did not indicate that the Angiomat 6000 has at least one mercury switch that communicates with the motor of the powerhead. This information was material to at least claims 1 and 9 of the '710 patent, in particular to the phrases "a tilt sensor" and "said control circuit being responsive to said tilt angle signal to determine a speed of motion of said motor" recited therein.

70. No prior art disclosed to the U.S.P.T.O. by Liebel-Flarsheim, the named inventors or Mr. Humphrey describes known, detailed functionalities of the Angiomat 6000 injector that were material to the subject matter of the ’288 application.

71. No prior art disclosed to the U.S.P.T.O. by Liebel-Flarsheim, the named inventors, or Mr. Humphrey discloses, for example, that once the injector is enabled, the membrane switches on the power head are disabled, such that only programmed injections can be performed (M00243031). This information is material to at least independent claim 9 and dependent claims 6 and 10 of the ’710 patent, and in particular, the limitations therein related to control of motor speed.

72. In disclosing the Angiomat 6000 marketing brochure to the U.S.P.T.O., Mr. Humphrey represented to the U.S.P.T.O. that the Angiomat 6000 injector was material to the prosecution of the ’288 application.

73. Mr. Humphrey, with an intent to avoid learning of information that might be material to the examination of the ’288 application and thereby intentionally withholding material information from the Examiner, did not inquire of each of the named inventors whether information was known regarding the features and functionalities of the Angiomat 6000 injector that was material to patentability. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp*, 267 F.3d 1370, 1381-86 (Fed. Cir. 2001); *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *21 (E.D. Tex. 2009).

74. From at least December 12, 1996 to February 9, 1999, Liebel-Flarsheim, and specifically Mr. Goethel, Mr. Neer, Mr. Verdino, Mr. Knipfer, Mr. Wagner and Mr. Humphrey, withheld at least the following Liebel-Flarsheim product manuals and specifications for the Angiomat 6000 during the prosecution of the ’288 application that they

each knew of with an intent to deceive the Examiner: (i) the Angiomat 6000 Digital Injection System, Installation and Service Manual 601910 (January 1992) ("Angiomat 6000 Installation and Service Manual"), (ii) the Angiomat 6000 Digital Injection System Operator's Manual 600981-C (January 1993) ("Angiomat 6000 Operator's Manual"), (iii) the Angiomat 6000 Parts Manual 600995 (December 1991) ("Angiomat 6000 Parts Manual"), or (iv) the printed circuits within the Liebel-Flarsheim Angiomat 6000 injectors distributed prior to November 22, 1995 ("the Angiomat 6000 printed circuit"). (Wagner Dep. Tr. 20:7-21:4)

75. The Angiomat 6000 Installation and Service Manual, the Angiomat 6000 Operator's Manual, the Angiomat 6000 Parts Manual, and the Angiomat 6000 printed circuit (collectively, "the Angiomat 6000 Manuals") are highly material to the subject matter of the '288 application.

76. In particular, the Angiomat 6000 Operator's Manual discloses, *inter alia*, an injector having a mechanism that moves a plunger, namely a plunger drive ram, and discloses that each injection is accomplished with microprocessor control of the flow rate, volume and timing provided by a motor-driven syringe. The Angiomat 6000 Parts Manual also expressly depicts a motor for moving said plunger drive ram.

77. The Angiomat 6000 Operator's Manual also discloses a syringe mounting means, in the form of a face plate, to attach to a syringe to position the plunger drive ram, and to engage and move a plunger.

78. The existence of at least one tilt switch in the Angiomat 6000 is confirmed by the statements in the Angiomat 6000 Operator's Manual at p. 4-46 (M00243079) explaining that, as an additional precaution against the injection of an air embolism, the software will check for the Required Fill Sequence, which requires the operator to move the powerhead to

the vertical position before allowing the injector to be enabled. This information was material to the patentability of at least claim 9 of the '710 patent, in particular, to the phrase "a tilt sensor" recited therein.

79. The Angiomat 6000 Operator's Manual further describes a control circuit, *i.e.*, microprocessor, that is in communication with a tilt switch and controls the movement and speed of the injector's motor. The Angiomat 6000 printed circuit and the Angiomat 6000 Parts Manual show at least one mercury switch tilt switch wired into the circuitry for controlling operation of the syringe drive to which the control circuit responded to determine the speed of motion of the motor. This information was material to the patentability of at least claim 9 of the '710 patent, in particular, to the phrases "a tilt sensor" and "said control circuit being responsive to said tilt angle signal to determine a speed of motion of said motor" recited therein.

80. The Angiomat 6000 Installation and Service Manual, which was withheld from the U.S.P.T.O., states at page 5-28 (M00241051), that "a tilt switch tells when the powerhead is tilted up or down." Moreover, the Angiomat 6000 Operator's Manual, which was also withheld from the U.S.P.T.O., discloses at page 4-46 (M00243079) that the injector software will check for a "Required Fill Sequence" before permitting the injector to be enabled, which requires the operator to run the plunger to zero, move the powerhead to the vertical position and retract the plunger back into the powerhead to fill the syringe. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular, to the phrase "a tilt sensor" recited therein. One of ordinary skill in the art would necessarily interpret the statements above quoted in paragraph 76 to indicate a tilt switch which

communicates with the control circuit to ensure that the powerhead is in the vertical position before allowing the injector to be armed.

81. The Angiomat 6000 printed circuit, which was also withheld from the Examiner, further shows a mercury switch wired into the circuitry for affecting and controlling the motor of the power head. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular, to the phrase "a tilt sensor" recited therein.

82. The Angiomat 6000 Operator's Manual discloses at p. 3-13 (M00243032), for example, that "[t]he Angiomat 6000 injector is equipped for variable speed filling." The Angiomat 6000 Operator's Manual further discloses at p. 3-13 (M00243032) that filling speeds (*i.e.*, when the power head is pointed upward) on the Angiomat 6000 could range from about 2-3 mL/second to approximately 25 mL/second. The Angiomat 6000 Operator's Manual discloses at p. 4-7 (M00243040) that injections (*i.e.*, when the power head is pointed downward) on the Angiomat 6000 injector could range in speed from 0.01 to 40 mL/second. Such injection speeds are both slower and faster than the filling speed (*i.e.*, when the injector is pointed upward). This information was material to the patentability of at least claims 1, 6, 9 and 10 of the '710 patent, in particular, to the phrases "a tilt sensor," "said control circuit responsive to said tilt angle signal to determine a speed of motion of said motor," and "wherein said control circuit operates said motor at a first speed if said tilt angle signal indicates that said injector is tilted upward with an outlet of said syringe elevated above said syringe, and said control circuit operates said motor at a second speed slower than said first speed if said tilt angle signal indicates that said injector is tilted downward with an outlet of said syringe positioned below said syringe" recited therein.

83. The Angiomat 6000 Installation and Service Manual, the Angiomat 6000 Operator's Manual, the Angiomat 6000 Parts Manual and the Angiomat 6000 printed circuit were thus material to the patentability of at least claims 1, 6, 9 and 10 of the '710 patent.

84. In contrast, the eight page Angiomat 6000 marketing brochure that Mr. Humphrey selectively disclosed to the U.S.P.T.O. on March 28, 1997 did not indicate that the injector included a tilt sensor of any kind or that the tilt sensor communicated with the motor of the power head.

85. Because the Angiomat 6000 manuals describe detailed specifications and functionalities of the Angiomat 6000 that are relevant to the claims of the '710 patent, and which were not disclosed by the Angiomat 6000 brochure that was submitted to the U.S.P.T.O., the Angiomat 6000 Manuals are not cumulative of the Angiomat 6000 brochure.

86. The Angiomat 6000 Manuals disclose a number of features and functionalities that are highly material to the claimed subject matter of the '710 patent, and are not cumulative of the prior art of record during the prosecution of the '288 application. The Angiomat 6000 Manuals describe, for example, that once the injector is enabled after performing the required fill sequence, the membrane switches on the power head are disabled, such that only programmed injections can be performed (M00243031). This information is material to at least independent claim 9 and dependent claims 6 and 10 of the '710 patent, and in particular, the limitations "said control circuit responsive to said tilt angle signal to determine a speed of motion of said motor," and "wherein said control circuit operates said motor at a first speed if said tilt angle signal indicates that said injector is tilted upward with an outlet of said syringe elevated above said syringe, and said control circuit operates said motor at a second speed slower than said first speed if said tilt angle signal indicates that said injector is tilted

downward with an outlet of said syringe positioned below said syringe" recited therein. This information is not cumulative of U.S. Patent No. 4,695,271 to Goethel or any of the other references cited during the prosecution of the '288 application.

87. The U.S.P.T.O. subsequently in a later filed reexamination of the '710 patent found that the Angiomat 6000 manuals were material to the patentability of the '710 patent and not cumulative of the prior art of record.

a. Specifically, on May 29, 2009, the U.S.P.T.O. granted E-Z-EM's Request for Reexamination of the '710 patent. The U.S.P.T.O. stated on p. 8 of its May 29, 2009 Order granting reexamination: "The Angiomat 6000 Operator's Manual and the Angiomat 6000 Parts Manual references [sic] is a new teaching, not previously considered nor addressed in the prior examination of the patent . . . It is agreed that the Angiomat 6000 Operator's Manual taken [sic] the Angiomat 6000 Parts Manual, raises an SNQ [substantial new question of patentability] with respect to claim 9."

b. The U.S.P.T.O. further stated on p. 8 of its May 26, 2009 Order granting reexamination: "The references considered during the prior examination do not disclose 'a tilt sensor in combination with a syringe and control circuit' as stated by the examiner during the prosecution of the application that became the '710 patent. Thus, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not these claims are patentable."

c. On September 26, 2009, the U.S.P.T.O. issued a first office action in the '710 patent reexamination, rejecting claims 9-11. The Examiner stated on pp. 4-5

of the September 26, 2009 office action that claim 11 is unpatentable as obvious in view of PCT patent application Publication No. WO 94/08647 to Ford *et al.* combined with the Angiomat 6000 Operator's Manual and the Angiomat 6000 Parts Manual.

88. By selectively disclosing only an eight page marketing brochure to the U.S.P.T.O. that provided only a limited technical disclosure, yet withholding or hiding from the U.S.P.T.O. more relevant, material and detailed technical information regarding operation and performance of the Angiomat 6000 that a reasonable Examiner would have considered to be important in deciding whether to allow the '288 application to issue as a patent, Liebel-Flarsheim, Mr. Goethel, Mr. Neer, Mr. Verdino, Mr. Knipfer, Mr. Wagner and their attorney Mr. Humphrey intentionally deceived the U.S.P.T.O. into issuing claims that they were not legally entitled to obtain, thereby committing inequitable conduct which renders the '710 patent unenforceable.

Plaintiffs and Their Attorney Withheld Material Information Regarding the Angiomat CT Injector With an Intent to Mislead the Examiner

89. Plaintiff Liebel-Flarsheim, and specifically James Goethel, Gary Wagner Dane Battiato, Steve Verdino, Charles Neer and their attorney, Mr. Humphrey, knowingly, willfully, and deliberately withheld or hid highly relevant and material information regarding Liebel-Flarsheim's own prior art Angiomat CT injector with an intent to mislead the Examiner into thinking that the Angiomat CT was less relevant than it actually was.

90. Mr. Goethel was the Project Manager, Angiography at Liebel-Flarsheim prior to the filing of the '710 patent.

91. Mr. Wagner worked in injector manufacturing at Liebel-Flarsheim prior to the filing of the '710 patent.

92. Mr. Battiato was a manager for Liebel-Flarsheim's injector products prior to the filing of the '710 patent.

93. Mr. Neer was the Manager of Electrical Engineering at Liebel-Flarsheim prior to the filing of the '710 patent.

94. Mr. Verdino worked in the service department as national tech support at Liebel-Flarsheim prior to the filing of the '710 patent. In his role as national tech support, Mr. Verdino read the product manuals for the Liebel-Flarsheim injectors, including the Angiomat CT, and trained Liebel-Flarsheim's field engineers.

95. Messrs. Goethel, Wagner, Battiato,Verdino and Neer had knowledge of relevant features and functionalities of the Angiomat CT that were material to the prosecution of at least independent claims 1 and 9 and dependent claims 6, 10 and 11 of the '710 patent.

a. Messrs. Goethel, Wagner, Battiato,Verdino and Neer knew prior to the Critical Date that the Angiomat CT included at least one mercury switch to detect the position of the powerhead.

b. Messrs. Goethel, Wagner, Battiato,Verdino and Neer knew prior to the Critical Date that the Angiomat CT included a "required fill sequence" which required the operator to run the plunger to zero, move the powerhead to the vertical position and retract the plunger back into the powerhead to fill the syringe.

c. Messrs. Goethel, Wagner, Battiato,Verdino and Neer knew prior to the Critical Date that the "required fill sequence" in the Angiomat CT used a mercury switch to detect the position of the powerhead.

d. Messrs. Goethel, Wagner, Battiato,Verdino and Neer knew prior to the Critical Date that the Angiomat CT could not be enabled to perform an injection unless the required fill sequence was first performed.

96. Despite Messrs. Goethel, Wagner, Battiato,Verdino and Neer having knowledge of the Angiomat CT and its relevant features prior to the Critical Date, they failed to provide to the U.S.P.T.O. known, detailed specifications and functionalities of the Angiomat CT which was material to the claimed subject matter of the ’288 application.

97. During the prosecution of the ’288 application, on March 27, 1997, Liebel-Flarsheim, through their attorney, Mr. Humphrey, selectively disclosed to the Examiner as prior art only a marketing brochure for the Angiomat CT that included a limited technical disclosure that omitted known, detailed specifications and functionalities of the Angiomat CT which corresponded to the claimed subject matter of the ’288 application. *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *20 (E.D. Tex. 2009) (holding that selective disclosure is strong evidence of intent to mislead the U.S.P.T.O.).

98. From at least December 12, 1996 through February 9, 1999, Messrs. Goethel, Wagner, Battiato, Verdino and Neer possessed or had access to but intentionally withheld from the U.S.P.T.O., more detailed and complete information regarding the Angiomat CT injector, including, for example, the Angiomat CT Digital Injection System 115 V, Installation and Service Manual for M3 Models 600980 (December 1988) (“Angiomat CT Installation and Service Manual”), the Angiomat CT Digital Injection System Operator’s Manual 600964-A (October 1990) (“Angiomat CT Operator’s Manual”), and the Angiomat CT Digital Injection System, Parts Manual 601935 (“Angiomat CT Parts Manual”).

99. The Angiomat CT Installation and Service Manual, the Angiomat CT Operator's Manual, and the Angiomat CT Parts Manual (collectively, "the Angiomat CT Manuals") are far more comprehensive and detailed than the Angiomat CT marketing brochure which Liebel-Flarsheim submitted to the U.S.P.T.O. The Angiomat CT Manuals thus are not cumulative of the Angiomat CT marketing brochure.

a. The Angiomat CT marketing brochure did not indicate that the injector included at least one mercury switch tilt sensor. However, the Angiomat CT Parts Manual, which was withheld from the U.S.P.T.O., discloses that the injector has a tilt switch inside the powerhead. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular to the phrase "a tilt sensor" recited therein.

b. The Angiomat CT Installation and Service Manual, which the Applicants failed to submit to the U.S.P.T.O., states at page 4-27 (M00026583) that "a tilt switch tells when the head is tilted up or down." Also, both the Angiomat CT Operator's Manual and the Angiomat CT Installation and Service Manual, which the Applicants also withheld from the U.S.P.T.O., disclose that the injector software will check for a "Required Fill Sequence" before permitting the injector to be enabled, which requires the operator to run the plunger to zero, move the powerhead to the vertical position and retract the plunger back into the powerhead to fill the syringe. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular to the phrase "a tilt sensor" recited therein.

c. One of ordinary skill in the art would necessarily understand that the statement in above paragraph 97(b) indicates a tilt sensor is in communication with the control circuit to ensure that the powerhead is in the vertical position before allowing the injector to be enabled. This information was material to the patentability of at least claims 1 and 9 of the ’710 patent, in particular to the phrase “a tilt sensor” recited therein.

100. In disclosing the Angiomat CT marketing brochure to the U.S.P.T.O. on March 27, 1997, Mr. Humphrey represented to the U.S.P.T.O. that the Angiomat CT injector was material to the prosecution of the ’288 application.

101. Mr. Humphrey, with an intent to avoid learning of information that might be material to the examination of the ’288 application and thereby intentionally withholding material information from the Examiner, did not inquire of each of the named inventors whether detailed information was known regarding the features and functionalities of the Angiomat CT injector that was material to patentability. *Brasseler, U.S.A. I, L.P. V. Stryker Sales Corp.*, 267 F.3d 1370, 1381-86 (Fed. Cir. 2001); *Golden Hour Data Systems, Inc. v. emsCharts, Inc.* No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *21 (E.D. Tex. 2009).

102. The Angiomat CT Installation and Service Manual, the Angiomat CT Operator’s Manual, and the Angiomat CT Parts Manual were material references to the prosecution of the ’288 application.

103. The Angiomat CT Operator’s Manual and the Angiomat CT Installation and Service Manual disclose, *inter alia*, an injector having an electric motor that moves a plunger, namely a plunger drive ram. The Angiomat CT Parts Manual similarly shows an electric motor for driving the drive ram.

104. The Angiomat CT Operator's Manual and the Angiomat CT Parts Manual also disclose a syringe mounting means, in the form of a face plate, for attachment to a syringe to position the plunger drive ram to engage and move a plunger.

105. The Angiomat CT Parts Manual shows at pages 2-26 and 2-29 (M00248020; M00248023) a mercury switch wired into the circuitry for controlling the syringe drive. The existence of a tilt switch in the Angiomat CT is further confirmed by the statements in the Angiomat CT Installation and Service Manual at page 4-27 (M00247233) explaining that a tilt switch in the power head tells when the head is pointing up or down as part of the loading and air expulsion protocol. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular to the phrase "a tilt sensor" recited therein.

106. The Angiomat CT Operator's Manual and the Angiomat CT Installation and Service Manual further describe a control circuit, *i.e.*, microprocessor, that is in communication with a tilt switch and controls the movement and speed of the injector's motor. This information was material to the patentability of at least claims 1 and 9 of the '710 patent, in particular to the phrases "a tilt sensor" and "said control circuit being responsive to said tilt angle signal to determine a speed of motion of said motor" recited therein.

107. The information disclosed in the Angiomat CT manuals was material and would have been important to the reasonable Examiner in determining whether to allow the '710 patent to issue, in particular claims 1 and 9 of the '710 patent.

108. The Angiomat CT Manuals disclose a number of features and functionalities that are highly material to the claimed subject matter of the '710 patent, and are not cumulative of the prior art of record during the prosecution of the '288 application. The Angiomat CT Manuals describe, for example, that once the injector is enabled after the required fill sequence

is performed, the membrane switches on the power head are disabled, such that only programmed injections can be performed. This information is material to at least independent claims 1 and 9 and dependent claims 6 and 10 of the ’710 patent, and in particular, the limitations “tilt sensor,” “said control circuit responsive to said tilt angle signal to determine a speed of motion of said motor,” and “wherein said control circuit operates said motor at a first speed if said tilt angle signal indicates that said injector is tilted upward with an outlet of said syringe elevated above said syringe, and said control circuit operates said motor at a second speed slower than said first speed if said tilt angle signal indicates that said injector is tilted downward with an outlet of said syringe positioned below said syringe” recited therein. This information is not cumulative of U.S. Patent No. 4,695,271 to Goethel or any of the other references cited during the prosecution of the ’288 application.

109. By selectively disclosing only a marketing brochure with a very limited technical disclosure on March 27, 1997 and yet withholding from the U.S.P.T.O. relevant, material and technically detailed information regarding the Angiomat CT that a reasonable Examiner would have considered to be important in deciding whether to allow the ’288 application to issue as a patent, Liebel-Flarsheim and specifically Messrs. Goethel, Wagner, Battiato, Verdino, Neer and Humphrey, intentionally deceived the U.S.P.T.O. into issuing claims which they were not legally entitled to obtain, thereby committing inequitable conduct which renders the ’710 patent unenforceable.

Plaintiffs and Their Attorney Withheld Material Information Regarding the CT 9000 Injector With an Intent to Mislead the Examiner

110. Plaintiff Liebel-Flarsheim and specifically James Goethel, Charles Neer Dane Battiato, Steve Verdino, Gary Wagner and James Knipfer and their attorney, Mr. Humphrey, knowingly, willfully, and deliberately withheld or hid relevant and material information

regarding Liebel-Flarsheim's own prior art CT 9000 injector with an intent to mislead the Examiner.

111. Mr. Goethel, Mr. Neer, Mr. Battiato, Mr. Verdino and Mr. Knipfer were involved in the development of the CT 9000 injector and had knowledge of its relevant features and functionalities prior to the Critical Date. (WHE016440, WHE016446-48; WHE016601) (Goethel Dep. Tr. 38:14-23; 39:23-40:1). Mr. Wagner was involved in the manufacturing of the CT 9000 injector and had knowledge of its relevant features and functionalities prior to the Critical Date. (Wagner Dep. Tr. 21:5-22:9; 136:24-137:1).

112. The CT 9000 injector was initially called the CT 8000 injector. (M-111663-111667)

113. Liebel-Flarsheim sold and/or offered for sale the CT 9000 in the United States more than one year prior to the filing date of the '710 patent (*i.e.*, prior to November 22, 1995), as evidenced by a 1992 Liebel-Flarsheim advertisement entitled "CT 9000 Contrast Delivery System" (EZ00810890-00810893) ("CT 9000 Advertisement").

114. Neither Liebel-Flarsheim nor Messrs. Goethel, Neer, Battiato, Verdino, Wagner or Knipfer nor their attorneys or representatives disclosed the CT 9000 injector to the U.S.P.T.O. during the prosecution of the '288 application. (Wagner Dep. Tr. 126:1-6; 128:22-129:7; 132:7-23).

115. Liebel-Flarsheim and, specifically, Messrs. Goethel, Neer, Battiato, Verdino and Knipfer and their attorney, Mr. Humphrey, withheld information regarding the prior sales and/or offers for sale of the CT 9000 referenced in above paragraph 111from the U.S.P.T.O. with an intent to deceive the Examiner during the prosecution of the '288 application.

116. From at least December 12, 1996 through February 9, 1999, Messrs. Goethel, Neer, Battiato, Verdino, Wagner and Knipfer possessed or had access to, but intentionally withheld from the U.S.P.T.O., information regarding the CT 9000 injector, including, for example, the CT 9000 Advertisement, the CT 9000 Digital Injection System Operator's Manual No. 800950 (M00258804-886) ("CT 9000 Operator's Manual"), and the CT 9000 Digital Injection System Installation, Service and Parts Manual No. 800951-A (M00257322-487) ("CT 9000 Installation Manual") (Wagner Dep. Tr. 34:10-12; 163:24-165:6).

117. Specifically, Messrs. Goethel, Neer, Battiato, Verdino, Wagner and Knipfer knew prior to the Critical Date that the CT 9000 included a hand-operated knob encoder on the power head that can be rotated in order to move the plunger drive ram forward or reverse. (Neer Dep. Tr. 124:14-125:6) (Wagner Dep. Tr. 25:21-27:19). This information is material to the first element of claim 7 which recites "a hand-operated movement control connected to said control circuit for generating a movement signal, said control circuit responsive to said movement signal to cause motion of said motor in a direction indicated by said movement signal."

118. Messrs. Goethel, Neer Battiato, Verdino, Wagner and Knipfer knew prior to the Critical Date that the CT 9000 also included a rotating electronic "beachball" symbol that, when injecting fluid, appears on the console's electronic display and spins as the injector is in the process of injecting to indicate the status of and state of operation of the power head at the time of injection. Mr. Wagner knew prior to the Critical Date that the graphic display associated with the CT 9000 console included a viewing angle adjustment. (Wagner Dep. Tr. 25:9-13; 31:7-32:6). This information is material to the limitation of claim 1 which recites "an

electronic display displaying information regarding the activities and state of operation of said injector," and to dependent claim 4 of the '710 patent, relating to graphics.

119. Liebel-Flarsheim has asserted that the CT 9000 injector is described in United States Patent No. 5,279,569 to Neer ("the Neer '569 patent")

120. Liebel-Flarsheim, through their attorney Mr. Humphrey, selectively disclosed the Neer '569 patent to the U.S.P.T.O. during the prosecution of the '288 application. *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *20 (E.D. Tex. 2009) (holding that selective disclosure is strong evidence of intent to mislead the U.S.P.T.O.).

121. In disclosing the Neer '569 patent to the U.S.P.T.O. on March 27, 1997, Mr. Humphrey represented to the U.S.P.T.O. that the injector described therein was material to the prosecution of the'288 application.

122. Mr. Humphrey, with an intent to avoid learning of information that might be material to the examination of the '288 application and thereby intentionally withholding material information from the Examiner, did not inquire of each of the named inventors whether detailed information existed regarding the material features and functionalities of the CT 9000 injector material to patentability. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1381-86 (Fed. Cir. 2001); *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *21 (E.D. Tex. 2009).

123. The CT 9000 Operator's Manual and the CT 9000 Installation Manual (collectively, "the CT 9000 Manuals") describe material features and functionalities of the CT 9000 injector which were not described in the Neer '569 patent, including an injector console

having a symbol "displayed during the Procedure Initiated screen to tell the operator that the injection is in progress" (M00257325).

124. The CT 9000 Operator's Manual and the CT 9000 Installation Manual are material and would have been important to the reasonable Examiner as they concern at least claims 1-8 of the '710 patent.

125. In particular, the CT 9000 Installation Manual is material to the limitation of claim 1 which recites "an electronic display displaying information regarding the activities and state of operation of said injector," and to dependent claim 4 of the '710 patent relating to display of graphics. The CT 9000 Installation Manual describes an injector console having a symbol displayed during the Procedure Initiated screen to tell the operator that the injection is in progress at p. iv (M00257325). This rotating electronic symbol is a pinwheel/beachball that spins as the injector is in the process of injecting indicative of the status of and state of operation of the power head at the time of injection. The operator of the injector is informed upon seeing the symbol rotating that an injection procedure is in action, and upon seeing the symbol stationary that an injection procedure is paused.

126. The CT 9000 Operator's Manual is also material to the first element of claim 7 which recites "a hand-operated movement control connected to said control circuit for generating a movement signal, said control circuit responsive to said movement signal to cause motion of said motor in a direction indicated by said movement signal." The CT 9000 Operator's Manual describes a hand-operated knob on the power head that can be manually adjusted and rotated moving the plunger drive ram forward or reverse to permit an injection (M00258826) (Neer Dep. Tr. 107:11-17; 124:14-126:4).

127. Mr. Humphrey also did not disclose U.S. Patent No. 5,662,612 (the "'612 patent") to the U.S.P.T.O. in connection with the '288 application. Mr. Humphrey knew of the '612 patent, indeed, Mr. Humphrey was the attorney who prosecuted the '612 patent.

128. The '612 patent discloses a manual knob of the CT 9000.

129. The manual knob of the CT 9000 as described in the '612 patent is a hand-operated movement control.

130. The manual knob of the CT 9000 as described in the '612 patent is information "a reasonable Examiner would be substantially likely to consider important in deciding whether to allow the application to issue as a patent. . ." when considering the claims that i0sued as Claims 7 and 11 of the '710 patent.

131. The CT 9000 Operator's Manual was also material to original claim 33 of the '288 application as filed.

132. Original claim 33 of the '288 application was directed to an injector having magnetic conductors for delivering magnetic fields from a powerhead face plate to detectors mounted on an internal circuit board to permit detection of different face plates.

133. Original claim 33 recited the following elements: a housing, a plunger drive ram mounted within said housing, a motor for moving said plunger drive ram, a face plate mounting on an external surface of said housing for receiving a detachable face plate used to position a syringe relative to said housing to permit said plunger drive ram to engage and move a plunger into or out of said syringe, said face plate including one or more sources of magnetic field energy, the presence or absence or orientation of said sources in a given face plate being indicative of attributes of said face plate and of a syringe type which can be mounted to said injector using said face plate, one or more magnetic conductors of magnetically permeable

material extending from said face plate mounting through said housing, positioned to channel magnetic field energy from said one or more sources into said housing, and a control circuit connected to said motor and controlling said motor to move said ram and plunger to inject fluid from said syringe, said control circuit including one or more magnetic field detectors positioned inside said housing adjacent said magnetic conductors to detect magnetic fields channeled into said housing by said magnetic conductors, said control circuit being responsive to said magnetic field detectors to identify a face plate mounted to said injector based on the presence or absence or orientation of magnetic field energy detected by said magnetic field detectors, and to move said motor in a manner appropriate for a syringe type which can be mounted to said injector using said face plate.

134. The ’710 patent specification discloses at Col. 3, line 67-Col. 4, line 5, “[O]ne feature of the inventive injector is the use of magnetic conductors to channel magnetic field energy from magnets positioned in the injector face plate, through the injector housing and into the vicinity of magnetic detectors (*e.g.*, Hall effect switches) mounted on the main circuit board.”

135. Mr. Neer and Mr. Wagner knew prior to the Critical Date that the CT 9000 included a Hall-effect sensor. (Neer Dep. Tr. 126:20-127:23) (Wagner Dep. Tr. 22:4-9; 25:13-20; 150:23-152:24).

136. The CT 9000 Installation Manual discloses an injector including all of the elements of original claim 33 and is thus material to the patentability of claim 33.

a. In particular, the CT 9000 Installation Manual discloses, *inter alia,* an injector having a housing in Figure 4-4.

b. The CT 9000 Installation Manual also discloses a CT 9000 power head with a face plate, a drive ram, and a motor-driven syringe mechanism at p. 1-1 and in Figure 3-9.

c. The CT 9000 Installation Manual also discloses a face plate at p. 5.

d. The CT 9000 Installation Manual further describes two Hall effect sensors connected to the power head circuit board which indicate whether the face plate is closed and indicate the syringe size at p. 3-35 (M00257376) ("There are two Hall effect sensors connected to the powerhead circuit board. The first sensor is connected to J1 and indicates if the face plate is closed. If the line connecting the sensor to the microcontroller is high, the face plate is not closed. If it is low, the face plate is closed. The second sensor connected to J12 determines the syringe size. If the line connecting the sensor to the microcontroller is high, it indicates a 200 mL syringe. If it is low, it indicates a 125 mL syringe.").

137. The CT 9000 Installation Manual is material and would have been important to the reasonable Examiner in considering the patentability of claim 33 of the '288 application, in particular to the phrase "a control circuit connected to said motor and controlling said motor to move said ram and plunger to inject fluid from said syringe, said control circuit including one or more magnetic field detectors positioned inside said housing adjacent said magnetic conductors to detect magnetic fields channeled into said housing by said magnetic conductors, said control circuit being responsive to said magnetic field detectors to identify a face plate mounted to said injector based on the presence or absence or orientation of magnetic field energy detected by said magnetic field detectors, and to move said motor in a manner

appropriate for a syringe type which can be mounted to said injector using said face plate" recited therein.

138. The applicants canceled claim 33 from the '288 application and subsequently re-filed it in a divisional patent application, namely U.S. Patent Application Serial No. 09/437,410, which issued as United States Patent No. 6,159,183 ("the '183 patent"). Original claim 33 of the '288 application issued as claim 1 of the '183 patent.

139. Plaintiffs continued to withhold the CT 9000 Manuals from the U.S.P.T.O. during the prosecution of the '183 divisional patent, thereby compounding the inequitable conduct they had committed during the prosecution of the '288 application.

140. Plaintiffs did not make any efforts to cure the inequitable conduct committed with respect to original claim 33 of the '288 application during the prosecution of the '288 application or during the prosecution of the related '183 divisional patent.

141. The U.S.P.T.O. has confirmed that the CT 9000 is material to the patentability of original claim 33 of the '288 application, which issued as claim 1 of the '183 divisional patent.

a. In a September 29, 2009 order granting the reexamination of the '183 patent, the Examiner stated that the CT 9000 Installation Manual raises a substantial new question of patentability regarding claim 1, as well as other claims, of the '183 patent.

b. None of the CT 9000 manuals were cited or considered by the U.S.P.T.O. during prosecution of the '288 application.

c. Specifically, the Examiner stated in the September 29, 2009 Order granting reexamination of the '183 patent:

> It is agreed that the CT 9000 Installation Manual raises a substantial new question of patentability regarding claims 1, 3 and 5 [of the '183 patent] as set forth in the request for reexamination on pages 7 and 17. For example, the CT 9000 Installation Manual teaches an injector comprising many of the claim limitations of claim 1 (see, e.g., pages 8-24 in the request), including a face plate (e.g., syringe plate assembly) that has a source of magnetic field energy (a magnet 13) (see Figures 2-1 on page 2-3 (page 123 out of 166 in IFW) and 2-8 on page 2-15 (page 135 out of 166 in IFW). Therefore, the CT 9000 Installation Manual provides teachings pertaining to at least one of the limitations argued [by the applicants] in the June 20, 2000 response to be missing from the prior art, which resulted in the allowance of the claims. In other words, the CT 9000 Installation Manual would be important to a reasonable examiner in deciding the patentability of the claims because it has teachings pertaining to face plate including the source of magnetic field energy, which seems to be pertinent to the reasons for patentability for the claims that issued in the '183 patent. As such, the CT 9000 Installation Manual presents a new technical teaching not clearly present [in] the prior art applied against the claims in the previous examination . . . Accordingly, a reasonable examiner would find the new teachings of the CT 9000 Installation Manual to be important in deciding whether or not a claim is patentable. Therefore, the CT 9000 Installation Manual raises a substantial new question of patentability regarding claims 1, 3 and 5 [of the '183 patent] for this reason.

142. The CT 9000 Operator's Manual was also material to original claim 34 of the '288 application as filed.

143. Original claim 34 of the '288 application was directed to a medical fluid injector having a "watchdog circuit." Specifically, the '288 application disclosed, *inter alia*, an injector having a monitor microcontroller for monitoring the behavior of the central processing unit to detect and react to error conditions.

144. Original claim 34 of the '288 application recited the following elements: a plunger drive ram, a motor for moving said plunger drive ram, a syringe mounting for attachment to a syringe to position a syringe relative to said injector to permit said plunger

drive ram to engage and move a plunger into or out of said syringe, a hand-operated movement control for generating a movement request signal indicating movements of said plunger drive ram desired by an operator, an encoder connected to said motor for generating a motion signal indicative of motion of said plunger drive ram, a motor control circuit connected to said motor, said hand-operated movement control and said encoder controlling said motor to move said ram and plunger to inject fluid from said syringe, said motor control circuit being responsive to said movement request signal to instruct said motor to move said plunger drive ram, said motor control circuit further generating a state signal indicating a state of operation of said motor control circuit for delivery through a monitor interface of said motor control circuit, said state signal indicating at least whether said motor control circuit is responding to said movement request signal by moving said motor, and a motor monitor circuit connected to said hand-operated movement control, said encoder and said monitor interface of said motor control circuit, monitoring said movement request signal, said motion signal and said state signal, said motor monitor circuit confirming that said state signal is consistent with said movement request signal and said motion signal, by at least confirming that when said movement request signal indicates that movements of said motor are desired, and said state signal indicates said motor control circuit is responding to said movement request signal to move said motor, said motion signal indicates said motor is moving in accordance with said movement request signal.

145. The CT 9000 Installation Manual is highly material to original claim 34 of the ’288 application. For example, CT 9000 Installation Manual discloses, *inter alia,* an injector including a monitor microcontroller for monitoring the behavior of the central processing unit to detect and react to error conditions, *i.e.,* a watchdog circuit.

a. In particular, the CT 9000 Installation Manual states at p. 3-2 (M00257343) "The main microprocessor writes a 12-bit word to a D/A. The resulting output voltage is input to a PWM (Pulse Width Modulator) circuit that controls a flyback regulator. The Flyback regulator generates a voltage which is applied to the motor. As the motor turns, an encoder on the motor provides a quadrature signal to the main microprocessor and the powerhead microprocessor. The main microprocessor compares the velocity of the motor, as derived from the motor encoder, to the desired velocity and adjusts the D/A output voltage accordingly. The powerhead microprocessor compares the velocity of the motor to a calculated velocity range. If the velocity is out of range the powerhead microprocessor will notify the main microprocessor and then stop the motor."

146. The CT 9000 Installation Manual is material and would have been important to the reasonable Examiner with respect to the patentability of claim 34 of the '288 application, in particular with regard to the phrase "a motor monitor circuit connected to said hand-operated movement control, said encoder, and said monitor interface of said motor control circuit, monitoring said movement request signal, said motion signal and said state signal . . ." recited therein.

147. Mr. Knipfer knew prior to the Critical Date of the '710 patent, November 22, 1995, that the CT 9000 included a watchdog circuit.

148. Liebel-Flarsheim canceled claim 34 from the '288 application and subsequently re-filed it in a divisional patent application, namely U.S. Patent Application Serial No.

09/447,101, which issued as the ’572 patent. Original claim 34 of the ’288 application issued as claim 1 of the ’572 patent.

149. Plaintiffs continued to withhold the CT 9000 Manuals from the U.S.P.T.O. during the prosecution of the ’572 divisional patent, thereby compounding the inequitable conduct they had committed during the prosecution of the ’288 application.

150. Plaintiffs did not make any efforts to cure the inequitable conduct committed with respect to original claim 34 of the ’288 application during the prosecution of the ’288 application or during the prosecution of the related ’572 patent.

151. By withholding highly material information regarding the CT 9000 injector, Liebel-Flarsheim and specifically Messrs. Goethel, Neer, Battiato, Verdino and Knipfer and their attorney, Mr. Humphrey, intentionally deceived the U.S.P.T.O. into issuing claims which they were not legally entitled to obtain, thereby committing inequitable conduct which renders the ’710 patent unenforceable.

Plaintiffs and Their Attorney Withheld Material Information Regarding the PercuPump II Injector With an Intent to Mislead the Examiner

152. Plaintiff Liebel-Flarsheim and specifically, named inventors James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern, and their attorney, Mr. Humphrey, knowingly, willfully, and deliberately withheld or hid information from the U.S.P.T.O. regarding Defendant E-Z-EM, Inc.’s material PercuPump II injector with an intent to deceive the Examiner.

153. Numerous Liebel-Flarsheim employees, including James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern, were knowledgeable of E-Z-EM, Inc.’s PercuPump II injector system and its

material features and functionalities prior to the filing date of the ’710 patent, and at least as early as May, 1995.

154. Two memos written by named inventor Steve Verdino state that Mr. Verdino observed and took notes on the features of the PercuPump II at trade shows prior to the Critical Date of November 22, 1995 (Verdino Dep. Tr. 147:2-149:4).

155. Mr. Verdino obtained information at various trade shows regarding E-Z-EM’s products, including E-Z-EM’s PercuPump II CT power injector. (Verdino Dep. Tr. 148:5-149:1).

a. Specifically, in a May 22, 1995 memo distributed to “APDT,” Mr. Verdino describes his “observations and notes” on the PercuPump II from the Society of Computed Body Tomography and Magnetic Resonance (“SCBT/MR”) medical show (M00172668-172676). At the SCBT/MR show, Mr. Verdino observed and studied features and functionalities of the PercuPump II that were material to the claimed subject matter of the ’288 application.

b. Mr. Verdino recognized that the PercuPump II included a means for detecting the tilt of the injector head as a safety feature (M00172668-172676) (Verdino Dep. Tr. 143:24-146:11).

c. In a June 26, 1995 memo distributed to “APDT,” Mr. Verdino describes his “observations and notes” on the PercuPump II and its relevant features and functionalities from the American Society of Radiologic Technologists (“ASRT”) show (M00030837-30839). At the ASRT show, Mr. Verdino observed and studied features and functionalities of the PercuPump II that were material to the claimed subject matter of the ’288 application.

d. The term "APDT" refers to Liebel-Flarsheim's Advanced Product Development Team (Fuller Dep. Tr. 26:2-27:8).

e. Robert Bergen, Pamela Jacobs, James Knipfer, Peter Staats, Mitchell Stern, Steve Verdino, and Gary Wagner were members of the APDT in May and June of 1995 (WHE100114; M00041566).

156. James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern further collected and exchanged material information regarding the PercuPump II and its material features and functionalities, including PercuPump II product literature and E-Z-EM's 510(k) submission to the Food and Drug Administration related to the PercuPump II prior to the filing of the '288 application and during its pendency.

157. James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern knew prior to the Critical Date that the PercuPump II included a tilt sensor in communication with the power head controls so that the power head's functions are affected by the angle of tilt of the power head.

158. James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern knew prior to the Critical Date that the PercuPump II included a control circuit connected to a motor that controls the movement and speed of the injection, and is affected by its mercury switches.

159. Despite being knowledgeable of the PercuPump II and its material features and functionalities prior to the filing date of the '288 application and during its pendency, James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern did not provide to the U.S.P.T.O. known, detailed specifications and

functionalities of the PercuPump II which corresponded to the claimed subject matter of the '288 application.

160. Liebel-Flarsheim received a facsimile dated June 22, 1995 from Medicor Belgium. The June 22, 1995 facsimile from Medicor included materials and information regarding E-Z-EM's PercuPump II and, specifically, indicated that the PercuPump II includes tilt sensors that prevent the injector from operating unless properly positioned to minimize the possibility of air embolism (M00424016-424022). These materials and information were included in Liebel-Flarsheim's training materials for its employees.

161. On May 3, 1996, Liebel-Flarsheim received by facsimile a sales brochure describing the features of the PercuPump II injector. Copies of this E-Z-EM PercuPump II sales brochure were included in Liebel-Flarsheim's training materials and competitor file. This sales brochure indicated that the PercuPump II includes a tilt sensor to reduce risk of embolism. Neither Liebel-Flarsheim nor James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, or Mitchell Stern nor their attorneys or representatives disclosed this PercuPump II sales brochure or any other information regarding the PercuPump II to the U.S.P.T.O. from December 12, 1996 through February 9, 1999, in violation of their duty of candor.

162. An internal Liebel-Flarsheim memorandum dated December 3, 1997 sent from Jim Knipfer to Dave Martino, Peter Staats and Dane Battiato states that Mr. Knipfer viewed the E-Z-EM PercuPump II device at the Radiological Society of North America ("RSNA") 1997 trade show. This memorandum also states that Mr. Knipfer searched for and obtained publicly available information related to E-Z-EM, Inc.'s 510(k) filing for the PercuPump II with Extravasation Detection Accessory ("EDA") at least as early as December of 1997.

163. Mr. Knipfer directed another Liebel-Flarsheim employee, Bridget Drake, to contact E-Z-EM, Inc. during the prosecution of the ’288 application to request a copy of the 510(k) Premarket Notification which E-Z-EM, Inc. submitted to the Food and Drug Administration (“FDA”) for the PercuPump II with EDA (M00006557). At Mr. Knipfer’s direction, Ms. Drake requested a copy of the 510(k) for E-Z-EM’s PercuPump II from E-Z-EM’s Director of Regulatory Affairs by letter dated December 5, 1997 (EZ00814549-50). E-Z-EM Inc.’s Director of Regulatory Affairs provided a copy of this documentation to Bridget Drake with a cover letter dated January 13, 1998 (M00006391).

164. Neither Liebel-Flarsheim nor Mr. Knipfer nor his co-inventors nor their attorneys or representatives disclosed E-Z-EM, Inc.’s 510(k) Premarket Notification or any other information regarding the PercuPump II to the U.S.P.T.O., in violation of their duty of candor.

165. In April, 1997, while the ’288 application was pending, named inventor Gary Wagner studied the PercuPump II and its relevant features and functionalities while attending a course held by the SCBT/MR. Mr. Wagner pretended to be a prospective buyer and observed a 15 minute demonstration of the PercuPump II and received PercuPump II product literature (M00350817).

166. During the prosecution of the ’288 application, on March 27, 1997, Liebel-Flarsheim, through their attorney, Mr. Humphrey, selectively disclosed to the Examiner as prior art a 1995 sales brochure entitled “Simply the Best Value in Low-Pressure CT Injection Systems, PercuPump 1A.” Notably absent was any disclosure or reference to the more pertinent PercuPump II injector. *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *20 (E.D. Tex. 2009).

167. In disclosing the PercuPump 1A brochure to the U.S.P.T.O., Mr. Humphrey represented to the U.S.P.T.O. that E-Z-EM's PercuPump 1A was material to the prosecution of the '288 application.

168. Mr. Humphrey, with an intent to avoid learning of information that might be material to the examination of the '288 application and thereby intentionally withholding material information from the Examiner, did not inquire of each of the inventors whether they had information regarding any of E-Z-EM's other products that would potentially be material to the prosecution of the '288 application. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1381-86 (Fed. Cir. 2001); *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, No. 06 CV 381, 2009 U.S. Dist. LEXIS 24225, at *21 (E.D. Tex. 2009).

169. The PercuPump II anticipates and includes all of the elements of Claim 9 of the '710 patent and thus would have been important to the reasonable Examiner in determining the patentability of the '288 application.

170. The PercuPump II is an injector which includes, *inter alia*, a plunger drive ram that moves the plunger in a syringe so that fluid can be dispensed.

171. The PercuPump II also includes a syringe mounting means, namely, a support that positions the syringe relative to the injector to permit the movement of the plunger in the syringe and a motor which moves the plunger drive ram.

172. The PercuPump II further includes tilt sensor mercury switches which are in communication with the power head controls so that the power head's functions and motor speed are affected by the angle of tilt of the power head. This information was material to claim 9 of the '710 patent, in particular to the phrase "a tilt sensor" recited therein.

173. The PercuPump II also includes a control circuit connected to a motor that controls the movement and speed of the injection, and is affected by its mercury switches. This information was material claim 9 of the ’710 patent, in particular to the phrases “a tilt sensor” and “said control circuit being responsive to said tilt angle signal to determine a speed of motion of said motor” recited therein.

174. The E-Z-EM PercuPump® II Touch*Screen™ CT Injector System, Manual and Operations Guide, 1995, confirms that the PercuPump II included each of the above-identified elements listed in paragraphs 168-171 above. As the PercuPump II injector anticipates and renders obvious at least Claim 9, it was clearly material to the prosecution of the ’288 application.

175. By withholding or hiding highly material information regarding the PercuPump II from the U.S.P.T.O., Liebel-Flarsheim, and specifically, James Knipfer, Dane Battiato, Peter Staats, Steve Verdino, Gary Wagner, Robert Bergen, Pamela Jacobs, and Mitchell Stern and their attorney, Mr. Humphrey, intentionally deceived the U.S.P.T.O. into issuing claims which they were not legally entitled to obtain, thereby committing inequitable conduct which renders the ’710 patent unenforceable.

Plaintiffs and Their Attorney Failed to Disclose to the U.S.P.T.O. During the Prosecution of the ’288 Application a Highly Material Written Opinion from the European Patent Office Regarding the Related ’027 PCT Application With an Intent to Mislead the Examiner

176. Plaintiff Liebel-Flarsheim, and specifically, Peter Staats and Dane Battiato, both of whom are named inventors on the ’710 patent, and their attorney, Mr. Thomas Humphrey, knowingly, willfully, and deliberately withheld from the U.S.P.T.O. during the prosecution of the ’288 application a written opinion issued by the European Patent Office with respect to the

'027 PCT application ("the EPO written opinion") with an intent to deceive the Examiner, as part of a continuing pattern of inequitable conduct.

177. The EPO written opinion stated, *inter alia*, that claims 21 and 29 of the '027 PCT application were not supported by the description and the disclosure of the specification.

178. The EPO written opinion stated at page 6:

> From the description and disclosure of the invention it is clear that an injector (20) is provided comprising among others a power head (22) and a console (24). It is thus clear that the term 'injector' denoted by reference sign (20) refers to an injector assembly comprising the said power head and console (both comprising a display). It is further clear that only tilting of the power head is relevant or contemplated. However, in the claims the term 'injector' is used to denote a tiltable structure (i.e., the power head), this is in contrast to the above. Claims 21 and 29 are thus not supported by the description as required by Art. 6. . . . In order to overcome the above objections, Claims 21 and 29 should be amended to define the relevant structures as set out in the description.

179. The '027 PCT application claimed priority to the '288 application and included claims that corresponded to one or more claims of the '288 application.

180. Claims 21 and 29 of the '027 PCT application were identical to claims 21 and 29 of the '288 application. Claims 21 and 29 of the '288 application issued as claims 1 and 9, respectively, of the '710 patent.

181. The European Patent Examiner read the claims as one of ordinary skill in the art and found that the term "injector" as used in Claims 21 and 29 of the '027 PCT application meant the injector head alone.

182. The European Patent Examiner found that the specification of the '027 PCT application referred to the injector as an injector assembly.

183. The European Patent Examiner concluded that the invention claimed in claims 21 and 29 of the ’027 PCT application was not the invention described in the specification of the ’027 PCT application.

184. Knowledge of the European Examiner’s interpretation of similar claims in the ’027 PCT application is material information that a reasonable Examiner would have considered important when examining the related ’288 application.

185. Mr. Humphrey received a copy of the EPO written opinion by letter dated September 15, 1998 from Alice Findlay of the law firm of Lloyd Wise, Tregear & Co.

186. Although Mr. Humphrey, Mr. Staats, and Mr. Battiato possessed the EPO written opinion and knew of its materiality during the prosecution of the ’288 application, neither Mr. Humphrey nor Messrs. Staats and Battiato nor anyone else acting on their behalf disclosed the EPO written opinion to the U.S.P.T.O. during the prosecution of the ’288 application.

187. In late 1998, Mr. Humphrey instructed the Lloyd Wise Tregear & Co. firm (“Lloyd Wise”) to respond to the Written Opinion dated September 10, 1998 in the ’027 PCT application. In the response that the Lloyd Wise firm filed, the patent owner, Plaintiff Liebel-Flarsheim, admitted that the alleged invention was “an injector assembly comprising a tiltable injector with the previously recited features.”

188. The December 9, 1998 response that the Lloyd Wise firm filed revised original application claim 21 which recited “An injector for injecting fluids from a syringe into an animal subject, comprising . . .” to instead read “An injector assembly (20) for injection fluids from a syringe (36) into an animal subject, having a tiltable injector comprising . . . .”

189. Although Messrs. Humphrey, Staats, and Battiato possessed the EPO written opinion and knew of its materiality during the prosecution of the ’288 application, neither Mr. Humphrey nor Messrs. Staats or Battiato nor anyone acting on their behalf disclosed the EPO written opinion to the U.S.P.T.O. during the prosecution of the ’288 application.

190. The failure of Messrs. Humphrey, Staats and Battiato to disclose to the U.S.P.T.O. during the prosecution of the ’288 application this highly material written opinion from the European Patent Office regarding the related ’027 PCT application with an intent to deceive the Examiner constitutes inequitable conduct which renders the ’710 patent unenforceable.

E-Z-EM’S COUNTERCLAIMS

Defendants/Counterclaim Plaintiffs bring these counterclaims against Plaintiff/Counterclaim Defendants Mallinckrodt Inc. and Liebel-Flarsheim Company.

COUNT I
Declaratory Judgment of Non-Infringement of U.S. Patent No. 5,868,710

191. E-Z-EM repeats and realleges paragraphs 1 –190 of this Fourth Amended Answer, Affirmative Defenses, and Counterclaims as if set forth fully herein.

192. An actual case or controversy exists between Defendant and E-Z-EM as to whether the ’710 patent is not infringed by E-Z-EM.

193. A judicial declaration is necessary and appropriate so that Defendant may ascertain its rights regarding the ’710 patent.

194. E-Z-EM has not infringed and does not infringe, directly or indirectly, any valid and enforceable claim of the ’710 patent.

195. This is an exceptional case under 35 U.S.C. § 285 because Plaintiffs filed their First Amended Complaint with knowledge of the facts stated in this Counterclaim.

COUNT II
Declaratory Judgment of Invalidity of U.S. Patent No. 5,868,710

196. E-Z-EM repeats and realleges paragraphs 1 –195 of this Fourth Amended Answer, Affirmative Defenses, and Counterclaims as if set forth fully herein.

197. An actual case or controversy exists between E-Z-EM and Plaintiffs as to whether the ’710 patent is invalid.

198. A judicial declaration is necessary and appropriate so that E-Z-EM may ascertain its rights as to whether the ’710 patent is invalid.

199. The ’710 patent is invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. § 101 *et seq*.

200. This is an exceptional case under 35 U.S.C. § 285 because Plaintiffs filed their First Amended Complaint with knowledge of the facts stated in this Counterclaim.

COUNT III
Declaratory Judgment of Unenforceability of U.S. Patent No. 5,868,710

201. E-Z-EM repeats and realleges paragraphs 1 –200 of this Fourth Amended Answer, Affirmative Defenses, and Counterclaims as if set forth fully herein.

202. An actual case or controversy exists between E-Z-EM and Plaintiffs as to whether the ’710 patent is unenforceable.

203. A judicial declaration is necessary and appropriate so that E-Z-EM may ascertain its rights as to whether the ’710 patent is unenforceable.

204. The ’710 patent is void, unenforceable and of no legal effect due to an ongoing and repeated pattern of inequitable conduct committed during the prosecution of the

application that matured into the ’710 patent. E-Z-EM repeats and re-alleges each of the allegations set forth in paragraphs 25 through 190 as though fully set forth herein.

205. This is an exceptional case under 35 U.S.C. § 285 because Plaintiffs knew, or should have known, of the facts stated in this counterclaim when Plaintiffs filed their original complaint as well as when they filed their First Amended Complaint.

RELIEF REQUESTED

WHEREFORE, E-Z-EM respectfully prays for judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, and/or sale of the EmpowerCT, EmpowerCTA and EmpowerMR injectors do not infringe, have not infringed, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’710 patent, nor has E-Z-EM induced or contributorily infringed any valid and enforceable claim of the ’710 patent;

(b) Declaring that the claims of the ’710 patent are invalid and unenforceable;

(c) Declaring that Plaintiffs’ claims are barred under the doctrine of laches;

(d) Declaring that the Plaintiffs’ claims are barred under the doctrine of equitable estoppel;

(e) Declaring that Plaintiffs’ claims are barred under 35 U.S.C. § 286;

(f) Declaring that Plaintiffs’ requests for damages are barred under 35 U.S.C. § 287(a);

(g) Awarding E-Z-EM its reasonable attorneys fees and costs under 35 U.S.C. § 285; and,

(h) Awarding E-Z-EM such other and further relief as the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

E-Z-EM hereby demands a jury trial for all issues triable by jury.

Dated this 13th day of May, 2010.

By: /s/ *Deron R. Dacus*

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed.R.Civ.P. 5(d) and Local Rule CV-5(e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of this document via email, facsimile and/or U.S. First Class Mail this 13th day of May, 2010.

/s/ Deron R. Dacus
Deron R. Dacus